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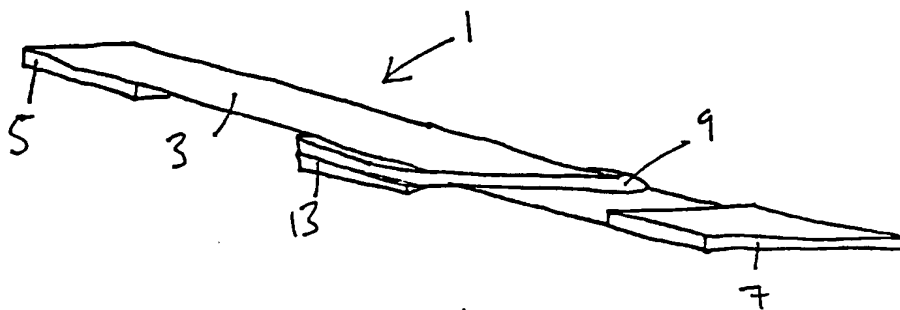


FIG. 1.

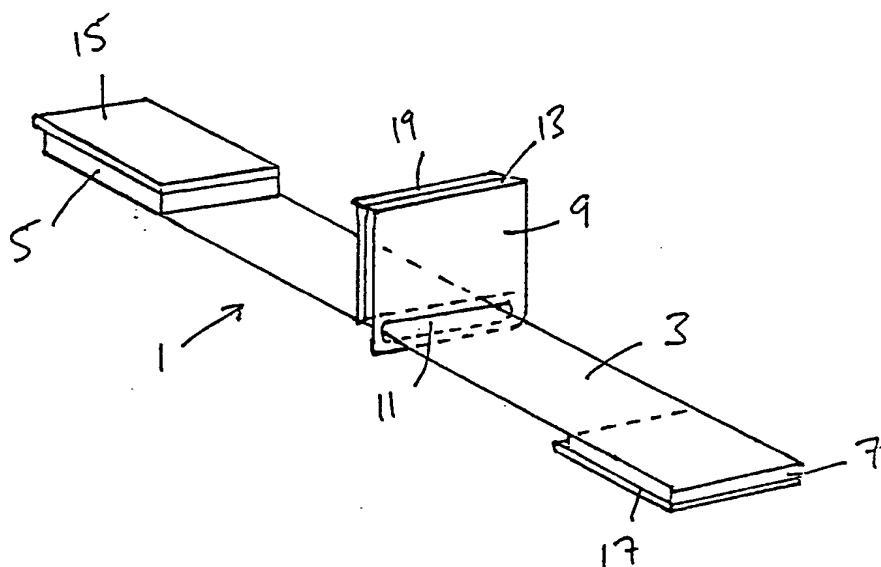
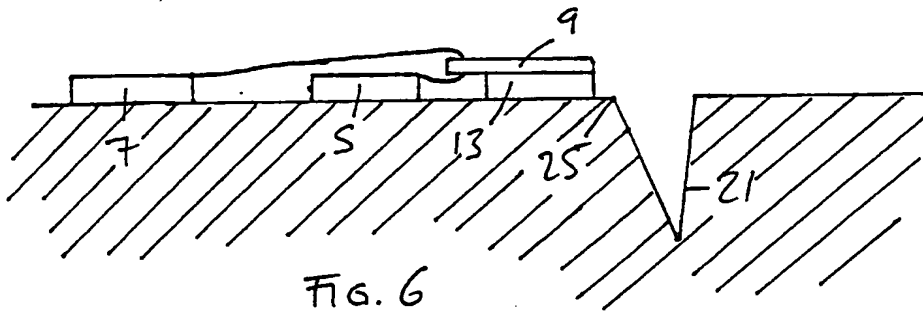
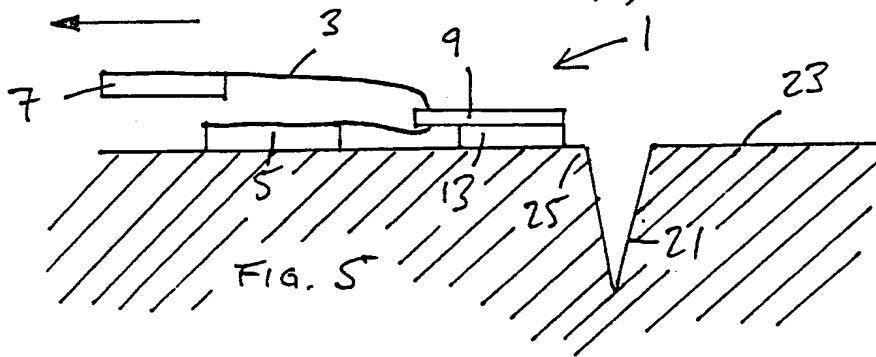
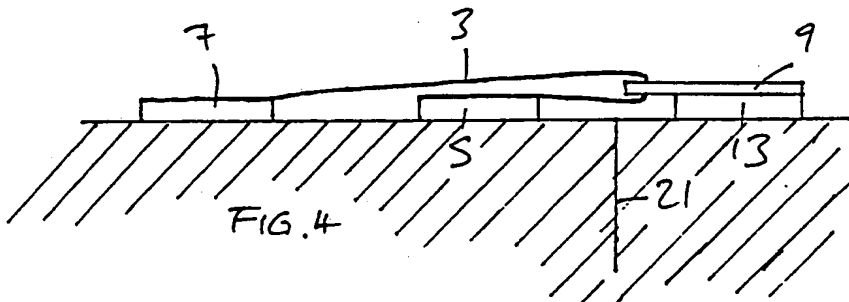
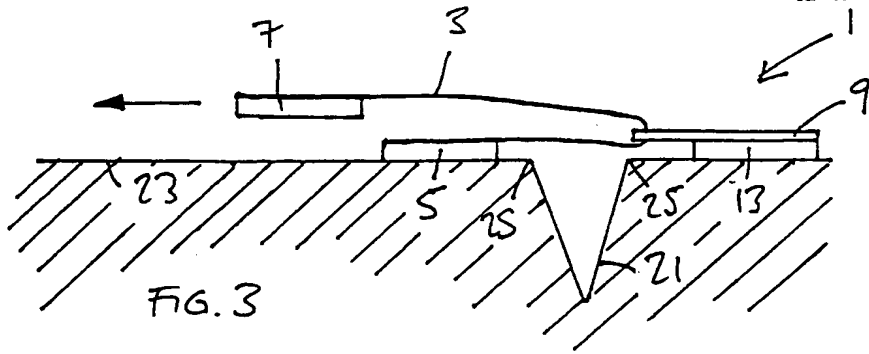


FIG. 2.

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SURGICAL DEVICE

This invention relates to a device suitable for closing or retracting an opening in tissue which in a particularly preferred embodiment resembles a strap and buckle arrangement, a first end of the strap and the buckle being attachable to skin on one side of the wound or across the wound, while the other end is used to draw the strap through the buckle and bring the first end and buckle closer together.

When the skin is broken to form a slit either by the result of an accidental wound or by the incision of a surgeon's knife during surgery the natural tendency of the skin is that the slit made will tend to close, particularly if the incision made results in a small slit in the skin. However, during surgery a surgeon performing an operation needs to obtain access at tissue through the incision. Thus, the surgeon requires a method of holding open the incision so that his hands are free to perform other steps of the operation. There are known in the art several devices which are called retractors, which are mechanical instruments or equipment which enables the slit in the skin to be held open during the operation. One such retractor is described in EP-A-0156218. This describes a retractor having a hook at one end for hooking onto an edge of the incision so the edges can be pulled back by the retractor, and at the other end the retractor has a pressure sensitive adhesive to adhere the retractor to the surrounding skin to hold the incision open once the edges have been retracted. However, such devices are limited to wound retraction only and cannot be used for holding the edges of the incision together

and thus closing the wound. The surgeon has to look for and use other devices (or even his or his assistant's hands) if he wishes to close an incision. Furthermore, the hook actually enters the incision and is intrusive into the tissue, so it is imperative that such devices are completely sterile.

Where a large incision has been made, or a portion of skin removed for example in an operation, then the natural tendency of the skin is for the edges of the incision to stay apart. Various attempts such as using surgical dressings which cover the whole wound or by using sutures are known to try and close the wound. Suturing involves the insertion of stitches to bridge the wound with the suture passing through the skin, the insertion of which may be painful and time-consuming. Sutures may also leave unwelcome scars and the removal of sutures often requires a nurse or doctor and the patient is not always able to remove the sutures himself. One device known in the art which attempts to maintain elongate slit-type wounds in a closed position is that described in GB-A-2083753. This device uses two pairs of adhesive strips, where one strip of each pair is placed either side of the wound, each strip being connected to its respective adhesive strip pair by a series of threads or filaments to bridge the wound. The latter adhesive strips are pulled away from each other which in turn pulls the respective adhesive strips either side of the incision closer together and thus closing the wound. However, such a device is complicated to manufacture and often expensive, and can be difficult to apply to the skin. Furthermore, its use is limited to closing incisions or slits in the skin and is inappropriate for holding slit wounds open.

There therefore exists a need for a simple device that is easy and cheap to manufacture and yet at the same time easy to use that can both hold open and close openings in tissue, e.g. slit wounds particularly during or after surgery.

Therefore according to the present invention there is provided a device suitable for closing or retracting an opening in tissue, the device comprising a first attachment means attachable at a first location on skin, the first attachment means being connected by a flexible member to a second attachment means, a third attachment means being movably coupled to the flexible member, the third attachment means being attachable to a second location spaced apart from the first location, and the second attachment means being movable to and attachable at a location to draw the first and second locations closer together.

The term opening is meant to cover any opening in skin such as an orifice, break, slit, incision or wound that either is accidental or is the result of surgery.

As used herein the term skin includes both human and animal skin. When used in a context of attachment, securement or adhesion to skin the term skin includes both direct and indirect attachment, securement or adhesion to the skin. Thus the device can be attached directly to bare skin or covered skin, for example covered by adhesive dressings, plaster, etc.

To use the device for closing an opening such as a wound the first and third attachment means are attached to the skin at first and second locations respectively on opposite sides of the opening. The second attachment means is moved away from the third attachment means which in turn pulls on the flexible

member movably coupled to the third attachment means, thus drawing the first and second locations closer together. When the desired degree of closure of the opening has been achieved the opening is held in this position by location of the second attachment means. The second attachment means is attached at a location which may be any one of or any combination of the skin, first attachment means and flexible member, and thereby secured.

To use the device for retracting an opening the same procedure is followed except that the first and third attachment means (and therefore the first and second locations) are on the same side of the opening. Usually the third attachment means is placed closer to an edge of the opening so that the flexible member does not bridge the opening thus allowing access to the tissue.

When the first and second locations are drawn together then either the first or second location may move towards the other, or both locations may move towards each other.

The distance between the first and third attachment means can be varied by movement of the second attachment means, so the wound may be opened or closed to a greater or lesser extent if desired. The second attachment means is attached (or re-attached) to the skin, flexible member or first attachment means where the positioning of the second attachment means determines the tension in the flexible member. The distance between the first and third attachment means is thus adjustable even when the device has been attached to the skin. This may even be done by the patient if necessary. There is therefore a very wide

range of distances that can be achieved between the first and third attachment means, the length of the flexible member permitting, almost to the extent that such distance is infinitely variable.

The device therefore serves the dual purpose of being both a wound retractor and closure device that has the advantages of a wound retractor and of a wound closure device and can be used by a surgeon during surgery to both open and close openings such as wounds without having to resort to different devices to do these two operations. Furthermore, the device of the present invention circumvents the use of sutures to close wounds and can be applied and removed by the patient himself.

The flexible member bridges the opening in the tissue when the device is being used as a closure device and at all times stays above the skin. In use, no part of the device penetrates the skin and all the attachment means and the flexible member when in use are on or above the surface of the skin. The flexible member, which is preferably substantially non-extensible, may be a thread, cord, filament, strip of material or a strap. It is preferred that when the flexible member is a strap or strip of material, it is made of a plastics material or a fabric. Where plastics materials are used these should be suitable for sterilization by methods known in the art such as heat treatment or by radiation such as gamma radiation. Furthermore, the plastics materials may be X-ray detectable, and thus at least partially opaque to X-rays. The flexible member may be transparent so the wound can be seen through the flexible member when closing a wound, allowing the surgeon to see when the desired degree of closure of the opening has been



achieved.

The attachment means encompasses any method of attaching the first, second or third attachment means directly or indirectly to the surface of the skin. Thus the attachment means may be clipped or locked to the skin using touch and close fasteners such as that sold under the trade mark VELCRO. In a preferred embodiment the attachment means is an adhesive means such as an area or pad having a region of pressure sensitive adhesive. This allows the second attachment means to be attached to any combination of the skin, first attachment means and flexible member. The pad may be any suitable (for example, plastics) material such as foamed polyethylene. The adhesive is preferably an acrylic based hypo-allergenic adhesive such as that used in the radiation tolerant, 3 mm polyethylene double-coated medical tape sold by the 3M company under number 1509.

The attachment means may also be two interlocking members, one of which is connected to the device while the other is applied, attached or adhered to the skin (for example a hook and eye arrangement). The attachment means may also be a clip means such as a spring clip or spring jaws adapted to clip resiliently onto the tissue for securing the appropriate portion of the device.

The third attachment means is movably coupled to the flexible member for example by way of a movable coupling means which acts as a guide for the flexible member. The movable coupling means provides a mechanical advantage and guides the flexible member so that as the second attachment means is pulled away from the third attachment means the elongate member passes

through or around the movable coupling means thus drawing the first and third attachment means closer together. The movable coupling means may be an annulus, hook, aperture, pulley, washer, clasp, ring or hoop but is preferably a slot or an eye. Thus the movable coupling means may be able to run loose along the flexible member. The movable coupling means and/or third attachment means are preferably made of a plastics material which may be the same as that used for the flexible member. It is preferred that the movable coupling means and third attachment means are integral so that in a particularly preferred embodiment the movable coupling means and third attachment means form a buckle. It is advantageous if the second attachment means can be attached to the skin beyond the first attachment means, that is to say further from the wound (that is being opened or closed) than the first attachment means. This can be achieved by making the elongate flexible member of an appropriate length. As a result the device may protrude little from the surface of the skin, in fact where a plastics strip is used in conjunction with adhesive pads, the device can be made thin and may sit flat and almost flush with the skin. When being used to close a wound, the device may be unobtrusive and the flexible member may provide protection for the wound.

The invention will now be described by way of example using the accompanying drawings, in which:

Figure 1 is a perspective view of a device in accordance with the present invention;

Figure 2 is another perspective view of the embodiment of Figure 1 but in a different configuration and with protective covers in place as on the adhesive

pads; and

Figures 3 to 6 are schematic side elevational/sectional views of the device of Figure 1 while in use.

In Figures 1 and 2 there is shown a device 1 comprising a flexible strip 3 of plastics material having at each end and on opposite sides two attachment means, namely a first and second adhesive pad 5 and 7 respectively. A buckle 9 which acts as a movable coupling means, also made of plastics material, is provided with a slit aperture 11 through which the strip 3 passes. The buckle 9 is provided with a third adhesive pad 13. For packaging purposes each adhesive pad 5, 7 and 13 is provided with a respective removable protective cover 15, 17, 19. This is to protect the adhesive pad from contamination and to ensure that each pad 5, 7 and 13 maintains its adhesive properties.

Prior to use each protective cover 15, 17, 19 is peeled off its respective adhesive pad 5, 7, 13. Figures 3 and 4 show two stages in the use of the device 1 in closing an opening in tissue such as a wound 21 while Figures 5 and 6 are concerned with opening a wound 21 and holding it open.

To close the wound 21 the first and third adhesive pads are pressed against and thus adhere to skin 23 either side of wound edges 25 at first and second locations respectively. By pulling the second adhesive pad 7 away from the third adhesive pad 13 (in the direction shown by the arrow) the strip 3 runs through the slit 11 thereby pulling the first and third adhesive pads 5 and 13 (and therefore the first and second locations) closer together. When the wound 21 has been closed, or the wound edges 25 are spaced apart

at a desired distance the second adhesive pad 7 is adhered at a location on the skin 23 by pressure. However, the second adhesive pad 7 may be adhered to another location such as the strip 3 or first adhesive pad 5 as desired. The wound 21 is thus closed and the device 1 may be removed when the wound 21 has healed. This can be done by the patient himself if necessary. Once the device 1 has been adhered to the skin 23 the tension in the strip 3 and distance between the first and second locations can be adjusted easily by moving the second adhesive pad 7 and re-adhering to the skin 23 or strip 3.

To use the device for holding a wound open the same procedure is followed as for closing the wound except that the first and third adhesive pads 5 and 13 are adhered to the skin 23 on the same side of the wound 21. If the third adhesive pad 13 is adhered nearest the wound edge 25 this configuration allows access to the wound 21.

CLAIMS

1. A device suitable for closing or retracting an opening in tissue, the device comprising a first attachment means attachable at a first location on skin, the first attachment means being connected by a flexible member to a second attachment means, a third attachment means being movably coupled to the flexible member, the third attachment means being attachable to a second location spaced apart from the first location, and the second attachment means being movable to and attachable at a location to draw the first and second locations closer together.

2. A device as claimed in Claim 1 wherein any number of the attachment means is an adhesive means.

3. A device as claimed in Claim 1 or 2 wherein the flexible member is a strip of material.

4. A device as claimed in any of Claims 1 to 3 wherein the flexible member is a strip of plastics material.

5. A device as claimed in any of Claims 1 to 4 wherein the attachment means is an area or pad having a region of pressure sensitive adhesive.

6. A device as claimed in any of Claims 1 to 5 wherein the third attachment means is movably coupled

to the flexible member by a movable coupling means which is a slot or eye.

7. A device as claimed in Claim 6 wherein the movable coupling means and third attachment means are integral.

8. A device as claimed in Claim 6 or 7 wherein the movable coupling means and/or third attachment means are made of a plastics material.

9. A device as claimed in any of Claims 1 to 8 wherein the movable coupling means and third attachment means form a buckle.

10. A device suitable for wound closure or retraction as herein described with reference to any of the accompanying drawings.